Treatment of neurogenic stress urinary incontinence using an adjustable continence device: 4-year followup

Mehnert, Ulrich ; Bastien, Laurence ; Denys, Pierre ; Cardot, Vincent ; Even-Schneider, Alexia ; Kocer, Serdar ; Chartier-Kastler, Emmanuel

Abstract: PURPOSE: We evaluated the long-term safety and efficacy of an adjustable continence device (ACT® or ProACT™) in male and female patients with neurogenic stress urinary incontinence. MATERIALS AND METHODS: Data on patients consecutively treated with implantation of an adjustable continence device due to neurogenic stress urinary incontinence were reviewed from the start of our experience to the current 4-year followup. RESULTS: We reviewed data on 13 male and 24 female patients with neurogenic stress urinary incontinence due to different forms of pelvic nerve or spinal cord lesions. Mean ± SD age at implantation was 46.2 ± 17.4 years. Of the patients 92% performed clean intermittent self-catheterization. The device was implanted bilaterally using general and local anesthesia in 16.2% and 83.8% of cases, respectively. From before implantation to 48-month followup the mean number of urinary incontinence episodes decreased from 6.1 ± 2.4 to 2.8 ± 3.1 and the mean number of pads used per 24 hours decreased from 4.2 ± 2.7 to 2.2 ± 2.2. Of the patients 54.5% indicated more than 50% improvement of stress urinary incontinence symptoms after 48 months, of whom 38.9% indicated complete continence. Adverse events included erosion/migration, device infection or failure, implantation site pain, bladder stone formation and difficult clean intermittent self-catheterization. CONCLUSIONS: Implantation of the ProACT/ACT device in patients with neurogenic stress urinary incontinence is minimally invasive and safe. It can significantly improve neurogenic stress urinary incontinence in the long term. Thus, it might be a reasonable option for patients who are not willing, not suitable or not yet ready for more invasive surgery, such as artificial urinary sphincter or fascial suspension sling placement.

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TREATMENT OF NEUROGENIC STRESS URINARY INCONTINENCE USING AN ADJUSTABLE CONTINENCE DEVICE: 4-YEAR FOLLOW-UP

Ulrich Mehnert[1], Laurence Bastien[1], Pierre Denys[2], Vincent Cardot[1], Alexia Even-Schneider[2], Serdar Kocer[3], and Emmanuel Chartier-Kastler[1,2]

1 Department of Urology and Renal Transplantation, Pitié –Salpêtrière Hospital, Pierre et Marie Curie Medical School, Paris VI University, Paris

2 Department of Physical Medicine and Rehabilitation, Raymond Poincaré Hospital, Paris Ouest Medical School, UVSQ, Garches, France

3 Department of Rehabilitation, Coubert Rehabilitation Center, Coubert, France

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ABSTRACT

Purpose: We evaluated the long-term safety and efficacy of an adjustable continence device (ACT® or ProACT®) in male and female patients with neurogenic SUI (nSUI).

Materials and Methods: Data on patients consecutively treated with implantation of an adjustable continence device due to nSUI were reviewed from the start of our experience to the current 4-year follow-up.

Results: We reviewed data on 13 male and 24 female patients with nSUI due to different forms of pelvic nerve or spinal cord lesions. Mean ± SD age at implantation was 46.2 ± 17.4 years. Of the patients 92% performed ISC. The device was implanted bilaterally using general and local anesthesia in 16.2% and 83.8% of cases, respectively. From before implantation to 48-month follow-up the mean number of urinary incontinence episodes decreased from 6.1 ± 2.4 to 2.8 ± 3.1 and the mean number of pads used per 24 hours decreased from 4.2 ± 2.7 to 2.2 ± 2.2. Of the patients 54.5% indicated more than 50% improvement of SUI symptoms after 48 months, of whom 38.9% indicated complete continence. Adverse events included erosion / migration, device infection or failure, implantation site pain, bladder stone formation and difficult ISC.

Conclusions: Implantation of the ACT® / ProACT® device in patients with nSUI is minimally invasive and safe. It can significantly improve nSUI in the long term. Thus, it might be a reasonable option for patients who are not willing, not suitable or not yet ready for more invasive surgery, such as AUS or fascial suspension sling placement.

Key words: urethra; prostheses and implants; stress urinary incontinence; spinal cord; treatment outcome

INTRODUCTION

Neurogenic lesions, e.g. SCI or peripheral lesions of nerve fibers innervating the LUT, can cause nSUI due to sphincter and / or bladder neck insufficiency. Managing neurogenic sphincter deficiency remains a therapeutic challenge since to our knowledge there is no available medical treatment. Moreover, most patients must perform ISC to empty the bladder and are at higher risk for complications of any prosthetic implant used for continence [1].

The current, most frequently used surgical options for nSUI are an AUS [2, 3] or an obstructing fascial sling [4-6]. However, these procedures require open abdominal and pelvic surgery using general anesthesia and do not provide the opportunity for postoperative adjustment. Some patients do not desire or feel uncomfortable with an AUS or they do not have the dexterity to use such an implant. Others might not be good candidates for more invasive surgery or they might need additional continence support after previous surgery, i.e. fascial sling placement. Moreover, in patients with nSUI it would be desirable to have an adjustable continence device that allows for adaptation in regard to changes in continence function without undergoing further surgery or changing the implant.

The ACT® / ProACT® device offers such adjustable continence support for male [7-10] and female [11] patients. The device consists of 2 balloons that are implanted in minimally invasive fashion on each side of the urethra. Small subcutaneous titanium ports allow refilling or deflation at any time. Good mid-term results with a 52% to 80% continence rate were achieved in non-neurogenic SUI populations with sphincter deficiency [7, 9-12]. However, long-term results of more than 2 years have been reported only for single cases.

There is no available information on using ACT® / ProACT® for nSUI. Thus, to our knowledge we retrospectively investigated for the first time the safety and efficacy of the ACT® / ProACT® device in male and female patients with nSUI.

PATIENTS AND METHODS

Data on patients who were consecutively treated at our clinic (Department of Urology, Pitié-Salpêtrière Hospital, Assistance Publique-Hôpitaux de Paris, University Paris VI) with implantation of the ACT® or ProACT® adjustable continence device due to nSUI were reviewed from the start of our experience up to the current 4-year follow-up to determine long-term results. The frequency of ISC, urinary incontinence episodes (UIEs) and pad use was evaluated from follow-up data and compared to preoperative values. In addition, balloon volume, operative and postoperative adverse events, and patient reported treatment outcomes were evaluated from follow-up data.

Statistical analysis was performed as applicable between pre-implantation and follow-up data using the Wilcoxon signed rank test with SPSS® 17.0.

RESULTS

A total of 13 male and 24 female patients with nSUI were treated with ACT® / ProACT® at our clinic. Mean ± SD age at implantation was 46.2 ± 17.4 years. Of the 37 patients 19 had paraplegia at Th3 or below, 7 had spina bifida, 4 had cauda equina syndrome and 1 each had poliomyelitis, syringomyelitis, lumbar stenosis, multiple sclerosis, tetraplegia, pelvic polytrauma and peripheral nerve lesion following major pelvic surgery, each with subsequent nSUI (**Table 1**).

A total of 14 patients received 1 or more previous urological treatments for nSUI, 21 underwent or were currently being treated for concomitant NDO and 5 received previous urological treatment for reasons other than nSUI or NDO (**Table 1**). Before implantation, the micturition mode was ISC and voluntary micturition in 34 and 3 patients, respectively. Additionally, 6 male patients used a condom catheter between ISC.

Urodynamic data before implantation revealed a mean maximum cystometric capacity of 424 ± 147 ml, a mean maximum detrusor storage pressure of 20.2 ± 11.3 cmH_2O and a mean bladder compliance of 37.7 ± 21.8 ml/cmH_2O. Mean urethral closure pressure was 22.6 ± 13.2 cmH_2O. DO or poor bladder compliance was not detected on pre-implantation cystometry, which was a prerequisite for the procedure. SUI was noted in each patient during pelvic examination.

All implantations were performed bilaterally under cystoscopic and fluoroscopic control by the same surgeon (ECK). All patients received prophylactic antibiotics at surgery. The detailed implantation technique was described previously [9-11]. The mean volume injected during implantation was 2.0 ± 0.3 and 1.9 ± 0.4 ml for the right and the left balloon, respectively. Mean operative time was 25 ± 2.4 minutes.

In 6 patients the procedure was performed under general anesthesia. All other patients tolerated implantation well under local anesthesia. Mean hospital stay was 1.5 days (range 1 to 2). However, this reflects an administrative rather than a medical reason.

During surgery or the postoperative hospital stay, a labial / scrotal hematoma developed in 2 patients, which was surgically removed in 1. In 3 patients small intraoperative urethral perforations resulted in immediate balloon repositioning on the side of the perforation and Foley catheter placement for 24 hours.

Follow-up was performed at 3, 6, 12, 24 and 48 months. Due to incomplete and missing data, 1 patient data set was excluded from further analysis. Thus, the data sets of 36 patients were used for follow-up analysis. By 48 months another patient was lost to follow-up and 1 each had died of esophageal cancer and cardiac arrest. Thus, at 48-month follow-up 33 patient data sets were available.

Table 1 Patient characteristics, previous and current urological treatments

Pt No. – Gender – Age [years] at implantation	Neurologic lesion (cause)	ASIA impairment scale/level of lesion	Previous urological treatments	Current urological treatments
1 – F – 72	Poliomyelitis		none	none
2 – F – 41	Paraplegia (infection)	A/Th9	Ileum bladder augmentation, suburethral sling from muscel fascia	oral oxybutynin
3 – F – 33	Paraplegia (vascular)	-/L5	none	oral oxybutynin
4 – F – 36	Paraplegia (trauma)	A/Th10	Botulinum toxin intradetrusor injections, Ileum bladder augmentation, trans vaginal tape	none
5 – M – 25	Syringomyelitis		none	oral oxybutynin
6 – M – 42	Spina bifida		Ileum bladder augmentation	none
7 – F – 49	Spina Bifida		Vesico-ureteral-reflux repair	none
8 – M – 69	Cauda-Equina-Syndrome (t)		Urethral stent, sacral neuromodulation	oral oxybutynin
9 – F – 55	Paraplegia (trauma)	A/Th12	trans vaginal tape	none
10 – F – 72	Cauda-Equina-Syndrome (Ca surgery)		sacral neuromodulation	none
11 – F – 37	Peripheral nerve lesion following major pelvic surgery		sacral neuromodulation	none
12 – M – 30	Spina bifida		Ileum bladder augmentation	none
13 – F – 68	Lumbar stenosis		Ileum bladder augmentation, trans vaginal tape	oral oxybutynin
14 – F – 46	Multiple sclerosis		Ileum bladder augmentation + continent urinary diversion, suburethral sling from muscle fascia	oral oxybutynin
15 - F – 32	Spina bifida		none	none
16 – F – 30	Paraplegia (trauma)	A/Th12	none	oral oxybutynin
17 – F – 26	Pelvic polytrauma		AMS800 (’88 – ’05), Ileum bladder augmentation, vesico-ureteral-reflux repair	none
18 – M – 62	Paraplegia (Ca surgery)	A/L1	Radical prostaectomy	oral oybutynin
19 – M – 55	Cauda-Equina-Syndrome		Orchiectomy	none
20 – M – 53	Paraplegia (trauma)	A/Th11	Ileum bladder augmentation, sphincterotomy	oral oxybutynin
21 – F – 58	Paraplegia	-/Th12	Promontofixation, bladder neck closure	oral oxybutynin
22 – F – 14	Spina bifida		Sigmoid cystoplasty, bladder neck reconstruction	none
23 – F – 46	Paraplegia (trauma)	A/Th11	Trans vaginal tape, hysterectomy, promontofixation, Ileum bladder augmentation + Mitrofanoff catherizable stoma	oral oxybutynin, intradetrusor injections with botulinum toxin
24 – F – 56	Paraplegia	A/Th12	Ileum bladder augmentation + Mitrofanoff catherizable stoma, trans vaginal tape	oral oxybutynin
25 – F – 64	Paraplagia (Ca surgery)	C/Th3	none	none
26 – F – 27	Paraplegia (trauma)	A/L1	suburethral sling from muscle fascia	none
27 – F – 83	Spina bifida		none	none
8 – F – 76	Cauda-Equina-Syndrome (Ca surgery)		none	none
29 – M – 36	Paraplegia (trauma)	D/Th12	none	none
30 – M – 30	Paraplegia (trauma)	A/Th12	vesico-ureteral-reflux repair, bladder stone extraction	none

Pt No. – Gender – Age [years] at implantation	Neurologic lesion (cause)	ASIA impairment scale/level of lesion	Previous urological treatments	Current urological treatments
31 – M – 71	Paraplegia (trauma)	A/Th10	none	none
32 – M – 36	Paraplegia (trauma)	A/Th10	none	none
33 – M – 44	Paraplegia (trauma)	A/L5	none	oral oxybutynin
34 – F – 41	Paraplegia (trauma)	A/L4	Promontofixation, trans vaginal tape	none
35 – F – 23	Spina bifida		Pippi-Salle procedure, trans vaginal tape	none
36 – M – 35	Tetraplegia		Urethral stent, urethrotomy	oral oxybutynin
37 – F – 35	Paraplegia (trauma)	B/L3	Promontofixation, trans vaginal tape	oral oxybutynin

F = female, M = male, ASIA = American Spinal Injury Association, L = lumbar, Th = thoracic

Table 2 lists balloon volume, the frequency of ISC, UIEs and pad use, and patient reported treatment outcomes. The micturition mode did not change in any patient postoperatively.

A total of 74 adverse events involved the 2 balloons or the balloon on only one side. Therefore, adverse events are not presented per patient but rather per balloon (**Table 3**). Overall, we noted device erosion/migration for 15 of the 74 balloons (20.3%), device infection for 5 (6.8%), implantation site pain for 5 (6.8%), and device failure (i.e. balloon leakage), bladder stone formation and difficult ISC for 2 each (2.7%). Balloons eroded / migrated more frequently into the urethra than into the bladder (13 vs 2 of 15). Adverse events were generally mild and only temporary due to easy, timely balloon explantation as an outpatient procedure without anesthesia. In cases of infection additional treatment with oral antibiotics was sufficient.

The number of patients who required or asked for device explantation was 5 of 36 (13.8%) at 3 months, 4 of 36 (11.1%) at 6 months, 2 of 36 (5.5%) at 12 months, 4 of 36 (11.1%) at 24 months and 9 of 33 (27.3%) at 48 months (**Table 3**). In 11 patients devices were only temporarily explanted and could be successfully re-implanted after 3 to 24 weeks (**Table 3**). Thus, the device was permanently explanted by the end of the 48-month follow-up in 13 of 33 patients (39.4%). Reasons for permanent removal were adverse events and the inefficacy of nSUI treatment.

Of the patients with permanently removed devices 4 underwent AUS implantation, 3 were treated with bladder neck closure combined with continent cutaneous urinary diversion and 2 received an ileal conduit.

DISCUSSION

The implantation of adjustable paraurethral balloons significantly decreased the number of UIEs and pad use in patients with nSUI. However, only 21% of patients attained complete continence and 39.4% required permanent explantation of the device after 4 years of follow-up. Nevertheless, greater than 50% improvement was reported by 67.6% and 64.8% of patients, including those who achieved complete continence, at 1 and 2 years of follow-up, respectively.

Table 2 Results on ballon volume, frequency of intermittend self-catheterization (ISC), urinary incontinence episodes (UIE), pad use, and patient reported outcome at baseline and follow-up after 3, 6, 12, 24, and 48 months.

	Baseline	Follow-up (months)				
		3	6	12	24	48
Mean ± SD balloon vol (ml):						
right		2.8 ±1.1	3.6 ±1.6	3.7 ±1.8	3.9 ±2.1	4.1 ±2.2
left		3.0 ±0.8	3.6 ±1.5	3.9 ±1.7	4.2 ±2.0	4.3 ±2.0
Mean ± SD No./24 hrs:						
ISCs	5.4 ±1.7	5.1 ±1.6,	5.0 ±1.7	5.2 ±1.7	5.2 ±1.9	5.6 ±1.7
UIE	6.1 ±2.4	3.9 ±3.2	4.1 ±2.9	3.1 ±3.4	3.2 ±3.4	2.8 ±3.1
p Value*		0.001	0.002	< 0.001	< 0.001	0.001
Pad use	4.2 ±2.7	2.3 ±2.2	2.4 ±2.3	1.8 ±2.0	2.4 ±2.5	2.2 ±2.2
p Value*		0.001	0.004	0.001	< 0.001	0.004
No. pt reported (%):		36	36	36	36	33
complete continence		6 (16.7)	6 (16.7)	7 (19.4)	5 (13.8)	7 (21.2)
50% or greater improvement		14 (39.0)	17 (47.2)	18 (50.0)	19 (52.8)	11 (33.3)
treatment failure or less than 50% improvement		16 (44.4)	11 (30.5)	8 (22.2)	7 (19.4)	2 (6)
permanent device explantation		0	2 (5.6)	3 (8.3)	5 (13.9)	13 (39.4)

* = significant different vs baseline

Previous groups that investigated the efficacy of the adjustable continence device in female and post-prostatectomy SUI cases reported a success rate of 52% to 80% (proportion of completely continent patients) [7, 9-12]. However, in the latter studies non-neurogenic patients had at least some sphincter and pelvic floor function remaining. In our patient population sphincteric and pelvic floor function was absent, explaining the discrepancy in efficacy rates between the current and previous studies. The type of neurological lesion might have influenced the results but this could not be statistically demonstrated in our study due to our small, mixed study population. However, according to daily clinical experience the degree of disability / mobility seems to be more important for the therapeutic outcome than the type of neurological lesion because there is high variability in nSUI severity even for the same type of neurological lesion.

Usually, postoperative adjustment is necessary to optimize the effect on urinary continence. Best outcomes were reported after 4 or 5 refillings [9]. In our patients refilling was done more rapidly during the first 6 months to achieve continence more quickly. Further refilling was needed less frequently and performed more cautiously to prevent trouble with ISC.

The most common intraoperative and postoperative complications using the adjustable continence device reported in the current literature are erosion in 2.5% to 7.5% of cases, urinary retention in 1.2% to 6.3%, migration in 3.8% to 5.6%, perforation in 2.5% to 18%, therapy failure in 2.5%, and urinary tract infections in 1.9% to 5% [7-12]. Other complications, such as wound infection in 0.6% to 8% of cases, implantation site pain in 0.6% to 15%, de novo urgency in 5% and device / material failure in 0.6% to 4% were less common [11] except in the study by Gilling et al. [7]. In most cases

complications were described as mild and quickly correctable. The reported explantation rate is between 8% and 58% [7-11]. Within 12 months after explantation successful reimplantation could be performed in most cases [11, 12].

Complication and explantation rates in our study of the ACT® / ProACT® device in an nSUI population are well within the ranges reported in the current literature. However, urinary retention is less relevant in our nSUI population of patients, who perform ISC. The fact that 92% of our patients performed ISC and 37.8% of them had undergone previous SUI surgery seems not to have negatively affected our complication rate.

Table 3 Adverse events in 74 ballon cases during follow-up

Follow-up (months)	No. Ballons*					No. Pts / No. Ballons	
	Errosion / Migration (site)	Infection (type)	Pain	Device failure	Other (cause)	Removal	Re-implantation
3	4 (urethra)	2 (device)		1 (balloon leak)		5 / 7	3 / 3
6	6 (5x urethra, 1x bladder)					4 / 7	3 / 5
12	1 (bladder)	1 (orchido-epidydimitis)	2		3 (2x bladder stone, 1x difficult ISC)	2 / 4	1 / 2
24	2 (urethra)	1 (device)	2	1 (balloon leak)	1 (difficult ISC)	4 / 7	3 / 5
48	2 (urethra)	1 (device)	1			9 / 17	1 / 1
Totals	**15**	**5**	**5**	**2**	**4**	**24 / 42**	**11 / 16**

*No patient had urethral stricture. ISC intermittend self-catheterisation

Concomitant NDO that is not treated or insufficiently treated can adversely influence the complication rate and study outcome in our patient population. Thus, in neurogenic cases it is important to strictly determine whether urinary incontinence is related to NDO or whether it is true SUI due to sphincter and / or bladder neck insufficiency [13]. This distinction can only be made by urodynamic investigations using filling cystometry, as in our study. All of our patients had cystometric parameters within the normal range and no DO. Those known to have NDO were under adequate treatment.

Other surgical therapies for SUI include bulking agents, suburethral or bladder neck slings / tapes and AUS implants. Bulking agents comprise different products of different materials, eg collagen, autologous fat, silicon, carbon, polytetrafluoroethylene and polyacrylamide hydrogel. Due to initially rather low therapeutic success and sparse data [14], this therapy form is not well established. There are hardly any investigations of the application of bulking agents for nSUI. Two studies in children with nSUI showed rather unsatisfactory results [15, 16]. Almost all bulking agents migrate, or cause erosion or granulomas [14, 17]. Re-injections are frequently required for adequate efficacy [14].

Autologous suspension slings, i.e. rectus fascia, are often used for female and male nSUI with a complete continence rate of 66.6% to 69.2% (mean 68.3%) in the adult population [4-6] and 14% to 95% (mean 68.4%) in the pediatric population [18-20]. However, most sling procedures are performed in combination with augmentation cystoplasty, which potentially contributes to the beneficial outcome of nSUI [19].

Although most patients with nSUI performed ISC, studies of autologous fascia slings in adult and pediatric patients with nSUI show only a few, less severe adverse events than those reported for tape and sling implantation in the more general SUI population [21, 22]. Two available studies show midterm and long-term outcomes of tension-free vaginal tape implantation in an adult female nSUI population with continence in 83.3% at 2 years [23] and in 77% at 10 years [13].

The AUS is used in men and less frequently in women [24, 25]. Due to its high efficacy in terms of the continence rate of 58% to 88% (proportion of completely continent patients), today it is the gold standard treatment for male SUI [26]. Patients with nSUI, in whom an AUS is an established treatment option, have also largely benefited from this therapy [24]. The success rate (proportion of completely continent patients) for nSUI is reportedly between 23% and 91% (mean 73%) [2, 27-30].

However, the AUS is expensive and requires a somewhat complex surgical procedure that may be associated with significant complication and revision rates [12]. Common complications are erosion, infection and mechanical / product related failure, causing an overall 16% to 80% revision and explantation rate [2, 28-30]. Murphy et al compared treatment outcomes between patients with nSUI and those with non-neurogenic SUI [27]. According to those results, patients with nSUI seem to have non-mechanical / non-product related complications more frequently, which was attributable to a higher rate of previous LUT surgeries in patients with nSUI. ISC and wheelchair dependency potentially also contribute to the higher complication rate in neurogenic cases.

Despite the rather average effectiveness in our study, special circumstances in patients with nSUI must be considered, such as complete sphincter insufficiency and a yawning bladder neck, i.e. in those with spina bifida. However, the adjustable balloons offer certain advantages. 1) Application is safe with few intraoperative and immediate postoperative complications even in neurogenic cases with previous LUT surgery. 2) The short, minimally invasive procedure allows for fast healing and a short hospital stay or even ambulatory treatment. 3) There is quick, uncomplicated ambulatory adaptation of balloon volumes according to patient needs [9]. 4) In contrast to slings / tapes or bulking agents, balloons can be explanted as ambulatory surgery using local anesthesia in case of adverse events with the option of re-implantation at 3 months. 5) Balloon implantation or explantation does not limit the implantation of other continence devices, i.e. an AUS, at a later time.

Although to our knowledge this is the first study evaluating the efficacy and safety of the ACT® / ProACT® system in an nSUI population, certain limitations must be considered. 1) Our study was not a randomized, prospective study. Nevertheless, our data are representative of everyday clinical practice. 2) Patient reported outcomes were not obtained anonymously from questionnaires but from chart reviews. 3) QoL before and after implantation was not systematically assessed and, therefore, could not be evaluated.

CONCLUSIONS

ACT® / ProACT® implantation in patients with nSUI can be performed as a short, minimally invasive procedure. The safety profile is good with intraoperative and postoperative complications that are self-limited or easily manageable, even in neurogenic patients who mainly performed ISC and / or underwent previous SUI surgery. Efficacy seems to be somewhat limited, probably due to the severity of the continence deficiency in neurogenic patients. Nevertheless, UIEs and pad use were significantly decreased throughout the 4-year follow-up. The ACT® / ProACT® system appears to be an interesting alternative for nSUI, especially for patients who need additional continence support after previous nSUI surgery or those who are not willing, not suitable or not yet ready for more invasive surgery.

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